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5.0 510(k) Summary of Safety and Effectiveness

DEC 2 2 2010

The following information is provided as required by 21 CFR § 807.87 for the ***BARD® DigniShield™ Stool Management System*** 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor:

BARD Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, Georgia 30014

Contact:

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Date of Submission: August 18, 2010

Proprietary Name: *BARD® DigniShield™ Stool Management System*

Common Name: Rectal catheter

Regulation: 21 CFR § 876.5980

Regulatory Class: II

Product Code: 78 KNT – Gastrointestinal tube and accessories

Predicate Device(s):

BARD® DigniCare™ Stool Management System	C. R. Bard, Inc.	K073598
ActiFlo™ Indwelling Catheter System Kit	Hollister Inc.	K083153

Device Description: The BARD® DigniShield™ Stool Management System is sold as a tray (kit). The catheter portion of the system consists of a retention cuff, a trans-

sphincteric zone and a drainage tube which are constructed from a Styrenic-based Thermoplastic Elastomer (TPE) material. The system includes a collection bag which is also manufactured from the same TPE material. Additionally, the tray (kit) contains stand alone finished components, a syringe, lubricating jelly, and an odor eliminator. The collection bag interfaces with the catheter and allows for the collection of the fecal matter. The syringe is used to facilitate the inflation of the retention cuff portion of the catheter. The lubricating jelly is provided to minimize patient discomfort and irritation of the rectum while the device is being inserted into the rectal vault.

The catheter is connected to a collection bag. When the catheter is disconnected from the collection bag, the self-sealing mechanisms of both the catheter and collection bag are engaged. This minimizes the leakage of fecal matter from either the catheter or the collection bag.

The device is single-use, non-sterile, and has no components made of natural rubber latex.

Intended Use: The *BARD® DigniShield™ Stool Management System* is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients.
Adult Use Only

Technological Characteristics Summary: The subject *BARD® DigniShield™ Stool Management System* has the same intended use, similar indications, technological characteristics, and principles of operation as the predicate devices. The only technological difference between the subject device and the DigniCare™ predicate device is that the catheter and collection bag material composition of the subject device is TPE and the predicate device catheter is silicone with a low density polyethylene collection bag. The use of the TPE material does not raise any new issues of safety or effectiveness. Therefore, the *BARD® DigniShield™ Stool Management System* is substantially equivalent to currently marketed fecal management systems.

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Performance Data Summary: Functional and structural integrity testing characteristic of devices of this type (e.g., tensile strength, dimensional, cuff inflation, etc.,), including biocompatibility testing in accordance with ISO 10993 has been performed on the subject device demonstrating that it is as safe and effective, and is substantial equivalent to legally marketed predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

C. R. Bard, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, N.W.
BUFFALO MN 55313

FEB - 9 2011

Re: K102391
Trade/Device Name: *BARD® DigniShield™ Stool Management System*
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: December 9, 2010
Received: December 10, 2010

Dear Mr. Job:

This letter corrects our substantially equivalent letter of December 22, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

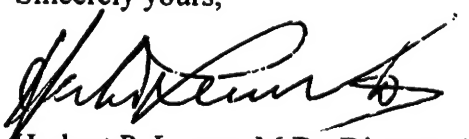
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102391 DEC 2 2 2010

Device Name: ***BARD® DigniShield™ Stool Management System***

Indications for Use: The ***BARD® DigniShield™ Stool Management System*** is intended for fecal management by diverting and collecting liquid or semi-liquid stool to minimize skin contact in bedridden patients.

Adult Use Only

Prescription Use: X AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K102391

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